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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/749,728	12/28/2000	Akihiro Umezawa	766.43	6784
5514	7590	11/16/2005	EXAMINER	
FITZPATRICK CELLA HARPER & SCINTO			WOITACH, JOSEPH T	
30 ROCKEFELLER PLAZA			ART UNIT	
NEW YORK, NY 10112			PAPER NUMBER	

1632

DATE MAILED: 11/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/749,728

Applicant(s)

UMEZAWA ET AL.

Examiner

Joseph T. Voitach

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,6-19,21-28,38,39,41,43,44,47-63 and 78-91 is/are pending in the application.
- 4a) Of the above claim(s) 47-63 and 78-91 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,6-19,21-28,38,39,41,43 and 44 is/are rejected.
- 7) ☒ Claim(s) 25 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 December 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 31, 2005 has been entered.

DETAILED ACTION

As indicated in the request for continued examination Applicants' after final amendment filed August 31, 2005 has been received and entered. Additionally, the preliminary amendment filed with the request for continued examination has been received and entered. The specification has been amended. Claims 2-5, 20, 29-37, 40, 42, 45, 46 and 64-77 have been cancelled. Claims 1, 6-19, 21-27, 38, 39, 41, 43, 44, 47-49, 51-61, 63, 78-86, 88-91 have been amended. Claims 1, 6-19, 21-28, 38, 39, 41, 43, 44, 47-63, 78-91 are pending.

Election/Restriction

Claims 1, 6-19, 21-28, 38, 39, 41, 43, 44, 47-63, 78-91 are pending. Claims 47-63 and 78-91 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 17.

Claims 1, 6-19, 21-28, 38, 39, 41, 43 and 44 are currently under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 6-19, 21-28, 38, 39, 41, 43 and 44 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn.

The amendment to the claims to encompass “more than one cell” addresses the basis of the rejection. It is noted that there is no literal support for the specific recitation found by examiner in the present specification, however the figurative support for differentiation into any cell type, and the multiple examples/recitations of more than one cell type is found to support the amendment.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 6-19, 21-28, 38, 39, 41, 43 and 44 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

The amendments to the claims deleting “derived” and providing proper antecedent basis for “the cell” have addressed the basis of the previous rejections

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 6-19, 21-28, 38, 39, 41, 43 and 44 stand rejected under 35 U.S.C. 102(b) as being anticipated by Klug *et al.*

Claims 1, 6-19, 21-28, 38, 39, 41, 43 and 44 stand rejected under 35 U.S.C. 102(b) as being anticipated by Juttermann *et al.*

Claims 1, 6-19, 21-28, 38, 39, 41, 43 and 44 stand are rejected under 35 U.S.C. 102(b) as being anticipated by Shi *et al.*

Claims 1, 6-19, 21-28, 38, 39, 41, 43 and 44 stand rejected under 35 U.S.C. 102(a) as being anticipated by Young *et al.*

Claims 1, 6-19, 21-28, 38, 39, 41, 43 and 44 stand rejected under 35 U.S.C. 102(a) as being anticipated by Makino *et al.*

Applicants note the amendment to the claim to indicate that the cell is obtained from bone marrow, and argue that the cited references fail to meet the limitations of the claims. See page 19 of Applicants' after final amendment. Applicants' arguments have been fully considered, but not found persuasive.

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It is noted again that the claims are given their broadest reasonable interpretation and that a claimed cell that meets the limitations set forth in the claim would anticipate the claim regardless of the source from which it is obtained. Unless the claims and/or the specification provides characteristics or some evidence that cells are different from those disclosed in the art, without a lab the office is left to maintain that meeting the characteristics set forth in the claim a cell from any source anticipates the claim. Moreover, Shi *et al.* and Makino *et al.* do teach stem cells isolated from bone marrow, and have demonstrated that they have the capacity to differentiate into cardiomyocytes. Applicants have argued previously that none of the cited references teach a bone-marrow derived stem cell that can differentiate into a cardiomyocyte and at least another cell type as required by the amended claims. (See Applicants' amendment to non-final office action, pages 17-18). To this arguments, the 102 rejections are maintained for reasons of record because the invention as claimed only requires the cells "can differentiate" into different cell types. With respect to the source from which is obtained, there is no particular nor specific limitation to the physical and/or functionally limitations required by the isolated cell set forth in the claims to differentiate it from the cells taught in the references cited. In this case, the various cells taught by Klug *et al.*, Juttermann *et al.*, Shi *et al.*, Young *et al.*, and Makino *et al.* anticipate the claimed cell because the claims fail to differentiate the claimed cell. For example, Klug *et al.* does teach a embryonic stem cells, not specifically a bone marrow cell, however stem cells can differentiate into cardiomyocytes and other cell types as required by amended claim 1, and are at least CD-34 positive (required of claim 9).

Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant

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to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See *In re Ludtke* 441 F.2d 660, 169 USPQ 563 (CCPA 1971). Whether the rejection is based on "inherency" under 35 USC 102, or "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. *In re Best, Bolton, and Shaw*, 195 USPQ 430, 433 (CCPA 1977) citing *In re Brown*, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972).

Conclusion

No claim is allowed.

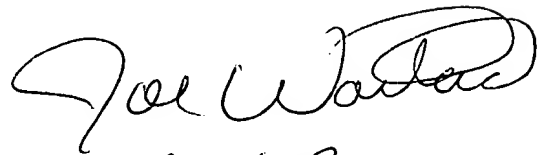
As indicated previously, claim 25 is objected to for being dependent on a rejected claim, however would be found allowable if rewritten in independent form.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach



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